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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,241	09/16/2003	Pal Maliga	RUT.97-0097US1-DIV	5658

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DANN, DORFMAN, HERRELL & SKILLMAN
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SUITE 2400
PHILADELPHIA, PA 19103-2307

EXAMINER

KUBELIK, ANNE R

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,241	MALIGA ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5 is/are rejected.
- 7) ☒ Claim(s) 6-9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-9 are pending. Claims 1-4 are withdrawn from consideration as being drawn to non-elected inventions.
2. This application contains claims 1-4 drawn to an invention nonelected with traverse in the response filed 18 August 2005. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. The objection to claims 6 and 7 because they start with an improper article is withdrawn in light of Applicant's amendment to the claims.
5. The rejection of claims 5-7 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment to the claims and arguments.

Claim Rejections - 35 USC § 112

6. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is modified from the rejection set forth in the Office action mailed 3 November 2005,

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as applied to claims 5-7, due to Applicant's amendment of the claims. Applicant's arguments filed 8 February 2006 have been fully considered but they are not persuasive.

A full review of the specification indicates that nucleic acids comprising NEP and PEP promoters are essential to the operation of the claimed invention. The level of skill and knowledge in the art at the time of filing was such that only a few of such promoters were identified; thus, there is no well-developed field of prior art.

The specification describes a NEP promoter consensus that is present in some, but not all NEP promoters (pg 21-22). No PEP consensus is described. Thus, the necessary and sufficient structural elements of the claimed promoters are not described within the full scope of the claims.

Hence, Applicant has not, in fact, described nucleic acids that comprise NEP and PEP promoters within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and functional characteristics of the claimed compositions, it is not clear that Applicant was in possession of the claimed genus at the time this application was filed.

Applicant urges that claims 6-7 have been amended to recite Prn instead of Prn-114 (response pg 5).

This portion of the rejection has been withdrawn.

Applicant urges that PEP promoters are described, including the rice rbcL promoter, the maize atpB promoter and the barley 16SrDNA promoter (response pg 8).

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This is not found persuasive because the full range of NEP and PEP promoters are not described. For example, that same passage of Example IV states that “in white albostrains seedlings lacking PEP it is transcribed from an uncharacterized NEP promoter”.

7. Claim 5 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for certain constructs comprising both NEP and PEP promoters, does not reasonably provide enablement for all constructs comprising both NEP and PEP promoters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is modified from the rejection set forth in the Office action mailed 3 November 2005, as applied to claims 5-7, due to Applicant's amendment of the claims. Applicant's arguments filed 8 February 2006 have been fully considered but they are not persuasive.

The claims are broadly drawn to any construct comprising both NEP and PEP promoters.

The instant specification, however, only provides guidance for analysis of plastid transcription in wildtype and *rpo*⁻ mutants, and the identification of NEP promoters from *clpP*, *rpoB*, *atpB* (example 1), and the PEP promoters from *clpP* (example 2-3); and promoter mapping in rice plastids (example 4).

The instant specification fails to provide guidance for NEP promoters from genes other than *clpP*, *rpoB* and *atpB*, and for PEP promoters from genes other than *clpP*.

As the specification does not describe NEP and PEP promoters within the full scope of the claims, undue trial and error experimentation would be required to screen through the myriad

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of nucleic acids encompassed by the claims, to identify those that are NEP and PEP promoters, if such plants are even obtainable.

Applicant urges that the specification teaches that Type I NEP promoters have significant homology with a certain sequence, and such promoters are taught from several plant species (response pg 7).

This is not found persuasive because the specification fails to provide guidance for NEP promoters from genes other than *clpP*, *rpoB* and *atpB*. Additionally, the level of homology required for a promoter to be an NEP promoter is not taught.

Applicant urges that *clpP* promoters are taught from several plant species (response pg 7).

This is not found persuasive because the specification fails to provide guidance for PEP promoters from genes other than *clpP*.

Applicant urges that PEP promoters are enabled, including the rice *rbcL* promoter, the maize *atpB* promoter and the barley 16SrDNA promoter (response pg 8).

This is not found persuasive because the full range of NEP and PEP promoters are not taught. For example, that same passage of Example IV states that “in white albastrains seedlings lacking PEP it is transcribed from an uncharacterized NEP promoter”.

Claim Rejections - 35 USC § 102

8. Claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by Maliga et al (US Patent 5,877,402, filed January 1994), taken with the evidence of Legen et al (2002, Plant J. 31:171-188). The rejection is repeated for the reasons of record as set forth in the Office action

mailed 3 November 2005. Applicant's arguments filed 8 February 2006 have been fully considered but they are not persuasive.

Maliga et al teach constructs comprising the *rps16* promoter operably linked to the *uidA* coding region (Fig 22A and C). Legen et al teach that this promoter comprises NEP and PEP promoters (paragraph spanning the columns on pg 179).

Applicant urges that Legen only says "Remarkably, ... *rps16* ... display[s] higher relative transcription rates in wildtype than in the mutant leaf tissue (see Figures 2a and 5a)" and does not teach that the *rps16* promoter is both a PEP and NEP promoter (response pg 10).

This is not found persuasive because lower expression in the PEP-lacking mutant indicates that *rps16* has a PEP promoter, as well as an NEP promoter.

9. Claims 6-9 are free of the prior art, given the failure of the prior art to teach or suggest a construct comprising a *Prn* promoter and either a *clpP*-111 or *clpP*-53 promoter operably linked to a protein coding sequence or *Prn* promoter of SEQ ID NO:32.
10. Claims 6-9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

11. No claim is allowed.
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached at (571) 272-0745.

The central fax number for official correspondence is (571) 273-8300.

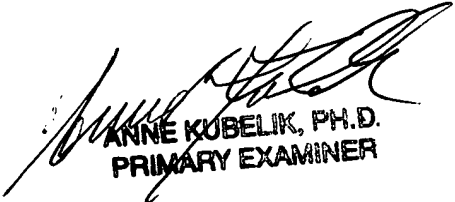
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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Anne Kubelik, Ph.D.

April 19, 2006



ANNE KUBELIK, PH.D.
PRIMARY EXAMINER